

Notice of Allowability

Application No.

10/628,525

Examiner

Samuel W. Liu

Applicant(s)

KEELING ET AL.

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 3/21/06.
2. ☒ The allowed claim(s) is/are 10,11,13-15 and 22.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date <u>4/5/06</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

Art Unit: 1653

DETAILED ACTION

The amendments filed 3/22/05, which amends claim 21 and cancels claims 1-9, 12 and 16-20, has been entered. Also, the applicants' request (filed 3/22/06) for extension of time of three months has been entered. Pending claims 10-11, 13-15 and 21 are examined in this Office action.

EXAMINER'S AMENDMENT

An Examiner's Amendment to the record appears below. Should the change and/or additions be unacceptable to Applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than payment of the Issue Fee.

Authorization for this Examiner's Amendment was given in a telephone interview with Patricia A. McDaniels on April 5, 2006. Applicants agree to the examiner proposed amendment to claims 10-11, 13-15 and 21 (see below).

Amendments to the claim:

The pending claims 20 and 30 have been amended as follows. Please replace the previous claims with the claims shown below.

Delete claim 21.

Add the following new claim.

Claim 22 (new) A recombinant nucleic acid construct comprising:

a) a promoter adapted to target expression of a payload polypeptide in a starch-containing tissue of a plant during starch formation, and

b) a nucleic acid sequence which is oriented 3' to said promoter encoding a hybrid polypeptide, said hybrid polypeptide comprising an N-terminal transit peptide having an amino acid sequence selected from the group consisting of SEQ ID NO: 33, SEQ ID NO: 34, SEQ ID NO: 35, SEQ ID NO: 35, SEQ ID NO: 36, and SEQ ID NO: 37; a starch-encapsulating region from maize starch synthase having an amino acid sequence 292-539 of SEQ ID NO: 21; and a payload polypeptide, wherein said payload polypeptide can be either N- or C-terminal to the starch encapsulating region.

Art Unit: 1653

In each of claims 10-11 and 13-15 which previously depend from claim 21 (now canceled) are amended to depend from the new claim 22 herein.

Amendment to the specification:

In abstract is amended as follows (in one paragraph):

The present invention relates to a recombinant nucleic acid encoding a hybrid polypeptide which comprises a transit peptide for the translocation of the polypeptide into an appropriate organelles such as plastids, a starch-encapsulating region from maize starch synthase and a payload polypeptide, wherein said payload polypeptide can be either N- or C-terminal to the starch encapsulating region. The invention also relates to the expression vectors comprising said nucleic acid, and hosts comprising the said vector. Also, the invention encompasses methods of producing the hybrid polypeptide thereof from starch and particularly from starch granules, and industrial uses of the payload polypeptide recombinantly produced in said hybrid polypeptide wherein said payload polypeptide is a biologically active molecule.

On page 11, line 7, "FIG. 1a" should be changed to "FIG. 1A".

On page 11, line 9, "FIG. 1b" should be changed to "FIG. 1B".

On page 11, line 10, "FIG. 2a" should be changed to "FIG. 2A".

On page 11, line 12, "FIG. 2b" should be changed to "FIG. 2B".

On page 11, line 14, "FIG. 3a" should be changed to "FIG. 3A".

On page 11, line 15, "FIG. 3b" should be changed to "FIG. 3B".

On page 12, line 1, "FIG. 7" should be changed to "FIG. 7A-7F"; and, lines 2-3, "FIG. 7a", "FIG. 7b", "FIG. 7c", FIG. 7d", FIG. 7e" and FIG. 7f", should be changed to "FIG. 7A", "FIG. 7B", "FIG. 7C", FIG. 7D", FIG. 7E" and FIG. 7F", respectively.

On pages 1-2 of the amended specification (filed 7/28/03), "SEQ. ID NO: " should be changed to "SEQ ID NO: ".

Conclusion: claims 10-11, 13-15 and 22 are allowed.

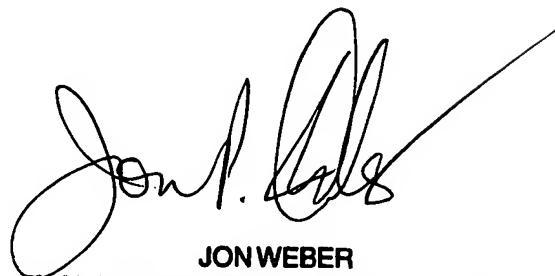
Art Unit: 1653

The following is an **Examiner's Statement of Reasons for Allowance**: The rejections under 35 USC 112, first and second paragraphs set forth in the Office action mailed 9/23/05 are withdrawn in light of that the applicants' amendment to claim 21 which obviates the rejections. The Prior art does not teach or suggest the claimed polynucleotide of claim 22 (previous claim 21) of the current invention. Thus, claims 1 and 10-12 are allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is (571) 272-0949. The Examiner can normally be reached daily except alternate Fridays from 8:30 A.M. to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Jon Weber, can be reached at (572) 272-0925. The official fax phone number for Technology Center 1600 is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.



Samuel W. Liu, Ph.D.
Art Unit 1653, Examiner
April 7, 2006



JON WEBER
SUPERVISORY PATENT EXAMINER

Abstract

The present invention relates to a recombinant nucleic acid encoding a hybrid polypeptide which comprises a transit peptide for the translocation of the polypeptide into an appropriate organelles such as plastids, a starch-encapsulating region from maize starch synthase and a payload polypeptide, wherein said payload polypeptide can be either N- or C-terminal to the starch encapsulating region. The invention also relates to the expression vectors comprising said nucleic acid, and hosts comprising the said vector. Also, the invention encompasses methods of producing the hybrid polypeptide thereof from starch and particularly from starch granules, and industrial uses of the payload polypeptide recombinantly produced in said hybrid polypeptide wherein said payload polypeptide is a biologically active molecule.